FEB 26 2014

510(K) SUMMARY

(DATE PREPARED: FEBRUARY 21, 2014)

Device Name
Surefire Guiding Catheter

Manufacturer Name and Address
Surefire Medical, Inc.
12415 SW 136 Ave., Unit 3
Miami FL 33186
Establishment Registration Number: 3009428975

Submitter Contact Information
Surefire Medical, Inc.
8601 Turnpike Drive, Suite 206
Westminster, CO 80031
Contact: Lynne Aronson, Director Regulatory Affairs
Phone: 303-426-1222 Fax: 303-426-1223

Common, Classification & Proprietary Names

Common Name:	Guiding Catheter
Classification Name:	Percutaneous Catheter
Proprietary Name:	Surefire Guiding Catheter
Classification:	Class II
Classification Panel:	Cardiovascular Devices
Classification Regulation:	21 CFR 870.1250
Product Code:	DQY

Predicate Device
- Medtronic Launcher Guiding Catheter K030779

Device Description
The Surefire Guiding Catheter provides a pathway to introduce and facilitate the advancement of devices into the peripheral vascular system.

The Surefire Guiding Catheter is a single-lumen, braided, fixed-length 5F catheter with a soft distal tip and a proximal Luer-Lock hub and strain relief. The Pebax extruded polymer is filled with a radiopacifier to provide visibility of the Surefire Guiding Catheter under fluoroscopy.

The Surefire Guiding Catheters are 65 and 80 cm in length with a variety of pre-shaped tip designs (including but not limited to Axis, Simmons 1 and Cobra) to accommodate access and positioning in a range of peripheral vascular anatomies. The distal tip is rounded for atraumatic tracking.

The Surefire Guiding Catheter is compatible with standard 0.038" OD guide wires, Luer-Lock infusion syringes, rotating hemostatic valves (RHV), and 5F catheter sheath introducers.

The Surefire Guiding Catheter is provided sterile (EtO) for single patient use

Indications for Use
The Surefire Guiding Catheter is intended to provide a pathway through which therapeutic devices are introduced. The Surefire Guiding Catheter is intended to be used in the peripheral vascular system.

Biocompatability Testing

Biocompatibility testing of the patient-contact materials used in the construction of the catheter was performed in accordance with ISO 10993-1 for an external communicating device in contact with circulating blood with a limited duration of less than 24 hours.

The following biocompatibility testing was conducted on the Surefire Infusion System (K110459), Surefire High-Flow Microcatheter (K121677), and Surefire Angiographic Catheter (K122506) which are constructed of the same materials as the Surefire Guiding Catheter. Therefore, the biocompatibility test requirements for the Surefire Guiding Catheter were met by leveraging previously completed biocompatibility testing.

All testing was performed in accordance with GLP by NAMSA (Northwood, OH).

Category	Standard	Test Method
Cytotoxicity	ISO 10993-5	Cytotoxicity Study Using the ISO Elution Method – 1x Minimal Essential Media Extract
Sensitization	ISO 10993-10	ISO Maximization Sensitization Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Maximization Sensitization Study – Extract – Sesame Oil, NF Extract
Irritation or Intracutaneous Reactivity	ISO 10993-10	ISO Intracutaneous Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Intracutaneous Study – Extract – Sesame Oil, NF Extract
Systemic Toxicity	ISO 10993-11	ISO Systemic Toxicity Study – Extract – 0.9% Sodium Chloride Solution Extract
		ISO Systemic Toxicity Study – Extract – Sesame Oil, NF Extract
		Pyrogen – Material Mediated – 0.9% Sodium Chloride Solution Extract
Hemocompatability	ISO 10993-4	ASTM Hemolysis – CMF-PBS Extract
		C3a Complement Assay – Normal Human Serum Extract
		SC5b-9 Complement Assay – Normal Human Serum Extract
		Coagulation – ASTM Partial Thromboplastin Time

Additionally, testing for thrombogenicity was performed on the Surefire Guiding Catheter as a part of the GLP Animal Study.

The results of all of the biocompatibility testing did not indicate any significant biological reaction that would affect the patient due to contact with the materials used in the device construction.

Performance Testing

Design verification testing was performed which demonstrated that the Surefire Guiding Catheter meets its specified performance requirements, and is equivalent to the performance of the predicate device. Testing included visual and dimensional inspection, and tests for particulates, kink, tensile strength, torque, trackability/device compatibility, high pressure injection, hub aspiration and flow/pressure generation.

Animal Testing

A GLP animal study was performed to assess the comparative acute performance of the Surefire Guiding Catheter to the predicate device, as defined by a physician in a clinical environment. The Surefire Guiding Catheter was found to have acceptable performance. Additionally, the Surefire Guiding Catheter was found to have comparable performance to the predicate device.

Substantial Equivalence

The Surefire Guiding Catheter is substantially equivalent in intended use, design, and technology/principles of operation to the predicate.

Comparative Summary: Design / Technological Characteristics

The Surefire Guiding Catheter and predicate device are single lumen catheters with Luer-Lock hubs and a variety of shaped tip styles. They have similar constructions consisting of a polymer outer extrusion with radiopacifier, stainless steel braid and polymer inner liner.

The Surefire Guiding Catheter and predicate device have similar dimensions, with inner and outer diameters that are consistent with a 5F sized catheter. Both catheters are available in a range of lengths. The predicate device is available in a longer length to accommodate use in the coronary application.

Comparative Summary: Indications for Use

The indication statement of the Surefire Guiding Catheter is the same as that of the predicate device with the exception that the predicate device is indicated for use in both the coronary and peripheral vascular system and the Surefire Guiding Catheter indication is limited to use in only the peripheral vascular system. As both devices are indicated for use in the peripheral vascular system, this difference in indications for use does not impact the safety and effectiveness of the Surefire Guiding Catheter when used as indicated.

Comparative Summary: Performance

Animal and bench performance test data demonstrate that the Surefire Guiding Catheter performance is comparable to the predicate device.

Differences between the devices do not raise any issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

Surefire Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K140034
Trade/Device Name: Surefire Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 4, 2014
Received: February 5, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140034

Device Name
Surefire Guiding Catheter

Indications for Use *(Describe)*

The Surefire Guiding Catheter is intended to provide a pathway through which therapeutic devices are introduced. The Surefire Guiding Catheter is intended to be used in the peripheral vascular system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Kenneth J. Cavanaugh -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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